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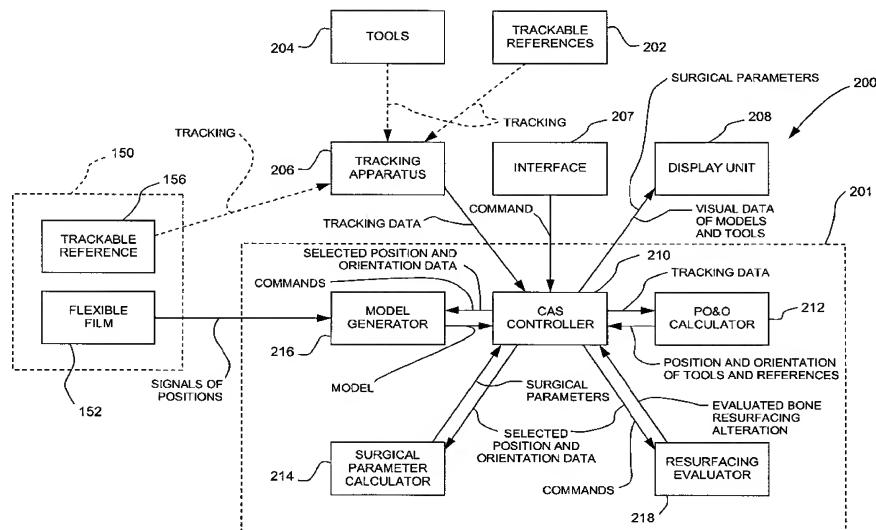
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(54) Title: COMPUTER-ASSISTED SURGERY TOOLS AND SYSTEM



(57) Abstract: A surface digitizing tool (150) has a film (152) of micro-sensor elements (152', 154), with each micro-sensor element (152', 154) related in a network affected by a shape of the film (152). The film (152) is flexible to conform to a shape of a selected surface of an object. A processing unit (201) receives signals from the micro-sensor elements (152', 154) of the network. The processing unit (201) has a model generator (216) producing a model of the selected surface of the object from the signals of the network of resistive elements. A positioning frame (170) aligns a position and orientation of a drilling tool with respect to a bone element.

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## COMPUTER-ASSISTED SURGERY TOOLS AND SYSTEM

## CROSS-REFERENCE TO RELATED APPLICATION

This patent application claims priority on United States Provisional Patent Application 5 No. 60/821,331, filed on August 3, 2006. This patent application incorporates by reference United States Patent Application Serial No. 11/339,499, by the present assignee, published as United States Publication No. 2006/0189864.

## 10 FIELD OF THE APPLICATION

The present application generally relates to Computer Assisted Surgery (CAS) such as hip joint resurfacing surgery and, more precisely, to a method for assisting hip joint resurfacing surgery and like 15 orthopaedic surgery with CAS systems.

## BACKGROUND OF THE ART

Orthopaedic surgery is constantly evolving to lessen the effects of surgery on patients. In order to reduce the amount of post-surgical pain, new methods and 20 tools have been developed in CAS to minimize the invasiveness of surgery. Moreover, CAS systems constantly involve new features to accelerate surgeries.

Also, CAS is more commonly used in surgical rooms, so as to provide precision and accuracy to the 25 surgeon. By way of CAS, position and orientation information is gathered during the surgical procedures, so as to provide to the surgeon real-time visual/digital data about bone alterations, tool navigation, and surgical parameters.

30 One of the issues pertaining to the efficiency of CAS is the creation of frames of references and the

digitization of bone models. In such cases, a plurality of points are digitized on the bone elements intraoperatively, which represents a time-consuming operation.

5 Hip joint resurfacing surgery involves the introduction of hip joint components in a patient. The acetabulum and the femoral head are resurfaced so as to receive an acetabular cup implant and a femoral head implant, respectively. The femoral head implant 10 consists of a ball head received at an end of the resurfaced femoral head. Therefore, the implanted femoral head and the cup (i.e., acetabular or pelvic implant) coact to create the artificial hip joint. In 15 comparison with total hip joint implanting surgery, the hip joint resurfacing surgery removes a relatively small amount of bone while preserving joint stability.

Different output values are of concern in hip replacement surgery. In order to reproduce a natural and/or improved gait and range of motion to a patient, 20 the position and orientation of the implants, the offset of the femur and the limb length must be considered during surgery. The work of the surgeon during hip replacement surgery will have a direct effect on these output values.

25 Known hip joint resurfacing surgery techniques presently involve specific tools so as to obtain precise position and orientation for the implants. As various types of reamers are used to resurface the femoral head, a plurality of alignment steps are performed to align 30 the tools with the cuts to be made. It is, for instance, of nonnegligible importance that the femoral neck not be damaged (i.e., notched) by the reamers, to prevent fracture-prone weaknesses in the femoral head. Moreover, the resurfacing must be as precise as

possible, for instance, to reduce the amount of cement required for implanting the ball head implant to the resurfaced ball head.

#### SUMMARY OF THE INVENTION

5 It is an aim of the present invention to provide a novel tool and system for digitizing bone surfaces in computer-assisted surgery.

10 It is a further aim of the present invention to provide a novel positioning frame for adjusting a position and orientation of bone-altering tools in computer-assisted surgery.

15 Therefore, in accordance with a first embodiment, there is provided a model generator system for generating models of objects, comprising: a surface digitizing tool having a film of micro-sensor elements, with each micro-sensor element related in a network affected by a shape of the film, the film being flexible to conform to a shape of a selected surface of an object; a processing unit for receiving signals from the 20 micro-sensor elements of the network, the processing unit having a model generator producing a model of the selected surface of the object from the signals of the network of resistive elements.

25 Further in accordance with the first embodiment, a tracking apparatus is provided, and the surface digitizing tool has a trackable reference connected to the film in a known relation, the trackable reference being tracked by the tracking apparatus; and the processing unit receives tracking data for the 30 trackable reference and further comprises a position/orientation calculator to calculate from the tracking data a position and orientation of the trackable reference, with the model generator receiving

said position and orientation data of the trackable reference to associate the position and orientation data to the known relation between the film and the trackable reference to provide a position and orientation of the 5 selected surface of the object.

Still further in accordance with the first embodiment, the tracking apparatus is a passive optical tracking apparatus, and the trackable reference is a selected pattern of retro-reflective spheres.

10 Still further in accordance with the first embodiment, the object is a bone element and the model generator system is used in computer-assisted surgery.

15 Still further in accordance with the first embodiment, the surface digitizing tool has a resilient body, the film of micro-sensors being mounted on the surface of the resilient body, the surface digitizing tool being used to conform to the shape of a bone element cavity with the resilient body deforming to enter the cavity and applying resilient forces against a 20 surface of the cavity, whereby the film of micro-sensors conforms to the shape of the cavity.

Still further in accordance with the first embodiment, the bone element cavity is an acetabulum.

25 Still further in accordance with the first embodiment, the surface digitizing tool is used with a bone element having a generally semi-spherical shape, and the processing unit has a center calculator for receiving the model of the selected surface of the bone element and determining a center of the bone element 30 from said model.

Still further in accordance with the first embodiment, the bone element is any one of an acetabulum and a femoral head.

Still further in accordance with the first embodiment, the micro-sensors are resistive elements.

Still further in accordance with the first embodiment, the micro-sensors are capacitive elements.

5        In accordance with a second embodiment, there is provided a positioning frame for aligning a position and orientation of a drilling tool with respect to a bone element, comprising: a connector portion adapted to releasably grasp the bone element; a support portion 10 operatively connected to the connector portion and positioned with respect to a portion of the bone element to be drilled; an alignment tube operatively connected to the support portion, the alignment tube being adapted to receive a working end of a drill to align the drill 15 with the bone element; and joints between the alignment tube and the connector portion to adjust a position and an orientation of the alignment tube with respect to the bone element.

Further in accordance with the second 20 embodiment, the joints comprise at least one joint providing at least two translational degrees of freedom between the connector portion and the alignment tube to adjust a position of the alignment tube, the two translational degrees-of-freedom being lockable.

25        Further in accordance with the second embodiment, degrees of actuation control and actuate the at least two translational degrees of freedom.

Further in accordance with the second 30 embodiment, the joints comprise at least one joint providing at least two rotational degrees of freedom between the connector portion and the alignment tube to adjust an orientation of the alignment tube, the two rotational degrees-of-freedom being lockable.

Further in accordance with the second embodiment, ends of the connector portions grasping the bone element each have a film of micro-sensor elements, with each micro-sensor element related in a network 5 affected by a shape of the film, the film being flexible to conform to a shape of the bone element so as to provide data pertaining to a geometry of the bone element.

Further in accordance with the second 10 embodiment, the bone element is a femur, and the connector portion releasably grasp a femoral neck of the femur, and the alignment tube is aligned with a femoral head of the femur.

Further in accordance with the second 15 embodiment, the joints provide four degrees of freedom between the alignment tube and the connector portion, with at least two degrees of actuation to actuate and control two selected ones of the degrees of freedom.

Further in accordance with the second 20 embodiment, the support portion has annular body, with the alignment tube being held generally in a center of the annular body, and wherein the connector portion has three legs projecting from the annular body.

In accordance with a third embodiment, there 25 is provided a method for drilling a bone element in computer-assisted surgery, comprising: providing a positioning frame having a drill guide with adjustable degrees of freedom for the drill guide in the positioning frame, and a computer-assisted surgery 30 system providing orientation data associated with tracking of the drill guide and of a frame of reference of the bone element; clamping the positioning frame to the bone element such that the drill guide is in the vicinity of a portion of the bone element to be drilled;

displacing the drill guide along the degrees of freedom as a function of the orientation data from the computer-assisted surgery, until a desired orientation is reached for the drill guide; and drilling the bone element by 5 passing a drill bit through the drill guide in the desired orientation.

Further in accordance with the third embodiment, displacing the drill guide comprises inserting a drill bit of a drill in the drill guide and 10 moving the drill and the drill guide concurrently.

Further in accordance with the third embodiment, providing orientation data comprises calculating the orientation data as a function of a tracking of the drill.

15 Further in accordance with the third embodiment, displacing the drill guide comprises locking the degrees of freedom at the selected orientation.

Further in accordance with the third embodiment, displacing the drill guide comprises 20 actuating degrees of actuation to actuate the degrees of freedom.

Further in accordance with the third embodiment, clamping the positioning frame comprises clamping the positioning frame to a femoral neck, such 25 that the drill guide is in the vicinity of a femoral head as the femoral head is drilled.

In accordance with a fourth embodiment, there is provided a method for generating a model of an object comprising: providing a film of micro-sensor elements, 30 with an individual position in the film of each said micro-sensor element known; obtaining a signal from each said micro-sensor element when the film is shaped to model an object; determining a shape variation of the film at each said micro-sensor element from the signal;

and generating a model of the object from the shape variation and the individual position of each said micro-sensor element.

Further in accordance with the fourth embodiment, providing comprises providing a trackable reference connected to the film of micro-sensor elements, with a relation between the film and the trackable reference known, and further comprising tracking the trackable reference, and calculating a position and orientation of the object from the model of the object and the tracking of the trackable reference.

Further in accordance with the fourth embodiment, obtaining comprises obtaining a signal from each said micro-sensor element when the film is shaped to model a bone element in computer-assisted surgery.

Further in accordance with the fourth embodiment, obtaining comprises obtaining a signal from each said micro-sensor element when the film is shaped to model at least one of a femoral head and an acetabulum in computer-assisted hip replacement surgery.

#### BRIEF DESCRIPTION OF DRAWINGS

Fig. 1 is a front elevation view of leg bones involved in a hip replacement method;

Fig. 2 is a flowchart of a method for hip joint resurfacing surgery;

Fig. 3 is a schematic view of a surface digitizing tool in accordance with a preferred embodiment of the present invention;

Fig. 4 is a block diagram of a hip resurfacing CAS system having a model generating system in accordance with another preferred embodiment of the present invention; and

Fig. 5 is a perspective view of a positioning frame mounted to a femur in accordance with another preferred embodiment of the present invention; and

5 Fig. 6 is a schematic view of a pattern of micro-elements as used in one embodiment of a flexible film of the surface digitizing tool of Fig. 3.

#### DESCRIPTION OF PREFERRED EMBODIMENTS

According to the drawings, and more particularly to Fig. 1, bones of the leg that will be 10 involved in the hip replacement surgery of the present embodiment are generally shown at 1. Fig. 1 is provided as reference for the description of the steps of the hip replacement surgery method described herein. The bones are the pelvis 10, the femur 20, the tibia 30 and the 15 fibula 40. Hereinafter, parts of these bones will each be referenced by numerals from the same numeric decade. For instance, parts of the pelvis (e.g., the acetabulum 11) will bear reference numerals between 11 and 14.

Referring to Fig. 2, a method for hip joint 20 resurfacing surgery in accordance with the present embodiment is generally shown at 100. Although the method 100 is referred to in the singular, various choices of procedure will be given to the surgeon, as will be set forth in the forthcoming description, 25 according to the preferences of the surgeon. A plurality of sequences can be derived from the method 100 according to the decisions of the surgeon.

In Step 102, preparative steps for surgery are 30 effected. Namely, general patient information can be entered into a CAS system for opening a patient file. For instance, a general patient profile can be entered, consisting of the name, birth date, identification number, sex and the like, the side to be operated, as

well as more specific data pertaining to the surgery, such as leg length discrepancy (with the identification of the longer leg), if applicable, and parameters to define the flow of the application and the display. For 5 instance, the leg length discrepancy is measured using X-rays of the hip joint. More precisely, the leg length discrepancy is measured from the vertical comparison between the lesser trochanters. These X-rays are typically taken during the diagnostic stages leading to 10 surgery, so they are usually available for hip joint surgery. Alternatively, X-rays may be taken as part of Step 102. It is also contemplated to import DICOM files or digital X-rays.

It is pointed out that the general patient 15 information can be entered preoperatively. Moreover, the entering of the general patient information is straightforward such that the surgeon need not be involved. However, in order to minimize the preoperative procedures, actions of Step 102 can be 20 performed at the beginning of the surgical session, during the short time span preceding the surgery.

Other values that will potentially be considered in the method 100 are inclination and anteversion for the pelvic implant, CCD (collodiaphyseal 25 angle) and anteversion for the femoral implant.

The calibration of the various surgical tools to be used is done. For instance, a calibration base and method, as set forth in U.S. Patent No. 6,996,487 by Jutras et al., can be used for the calibration. 30 Also, correspondence between the tracking of the tools and the display on a CAS system can be verified in further calibration steps included in Step 102. A permanent calibration system can also be used, as set forth in International Publication No. WO 2005/102202.

Surgery is initiated between Step 102 and subsequent Step 104, by the surgeon exposing the hip joint. No computer assistance is required thereat.

In Step 104, the trackable references are 5 secured to the pelvis with a pelvic modular reference, and to the femur with a femoral modular reference. The pelvic modular reference can be inserted in a cranial or lateral position. Alternatively, the trackable references may be secured prior to exposing the hip 10 joint.

It is pointed out that the pelvic modular reference, in a preferred embodiment, is positioned while the patient is in supine decubitus. Moreover, as will be described hereinafter, the pelvic coordinate 15 system and table reference must also be digitized in supine decubitus. After those manipulations, the patient can be repositioned in lateral decubitus.

The femoral modular reference can be inserted at the proximal third from the femoral head of the femur 20 or at the distal third from the femoral head. These insertion points are examples, as any other suitable point on the femur is considered. Positions of the trackable references are, for example, (1) looking posterior and towards the head, prior to dislocation, 25 and (2) a longer trackable reference, looking posterior, for the dislocated position. It is contemplated to use a single modular base.

In Step 106, it is contemplated to digitize the coordinate system in lateral decubitus. It is also 30 contemplated to collect posture information, as described in International Publication No. WO 2004/030559 A1, by Jansen et al. Criteria may be used to validate the points taken and the computed surface.

In Step 106, a pelvic coordinate system and a femoral coordinate system are digitized. In an embodiment, the pelvic coordinate system is digitized with a registration pointer. In an embodiment, three 5 points are taken on the pelvis 10 to create the frontal plane of the acetabular coordinate system. Referring to Fig. 1, there is one point on the iliac crest 12 of the operated side, one point on the contra lateral iliac crest 13, and one point on one of the two pubic 10 tubercles 14 of the pelvis 10. To be generally aligned, the points digitized on the iliac crests 12 and 13 are taken at the outermost anterior point of the iliac crests 12 and 13. The points digitized on the iliac crests 12 and 13 are preferably taken directly on the 15 soft tissue covering the bone pelvis on the iliac crests, as the soft tissue is relatively thin thereon. The point on the pubic tubercle 14 completes a first plane, the frontal plane. A second plane, the transverse plane, is perpendicular to the frontal plane 20 and includes the points on the iliac crests. A third plane, the sagittal plane, is perpendicular to the frontal and transverse planes.

Supplemental information regarding the frontal plane can be obtained for various postures of a patient. 25 For instance, trackable references can be used to gather information about sitting, standing and walking postures. This information can be used to adjust the orientation of the frontal plane, as these postures can provide information not available from the typical lying 30 posture in which a patient is during surgery. This information can influence the anteversion positioning of the implants.

It is possible to obtain anteversion and/or inclination values of the acetabulum of the patient, to

be used as a reference (e.g., comparison basis) later in the surgery. To do so, points are digitized using a registration pointer on the generally circular edge of the acetabulum 11 and a plane is defined from these 5 points. A normal to this plane and the pelvic frontal plane give the anteversion angle. The normal to this plane is projected onto the acetabular frontal plane to give an inclination angle with a cranial-caudal axis.

For the digitization of the femoral coordinate 10 system, it is contemplated to collect five points of reference on the leg to the CAS system, which is equipped with software that will create the femoral coordinate system.

Referring to Fig. 1, a first point is taken on 15 the tip of the greater trochanter 23 of the femur 20, and will be defined as a starting point of an anatomical axis of the femur 20. Thereafter, points are taken on the medial and lateral epicondyles 24 and 25 of the femur 20, respectively. A midpoint between the medial 20 epicondyle and lateral epicondyle points, in alignment therewith, is defined as an endpoint of the anatomical axis of the femur. The fourth and fifth points are taken on the medial malleolus 31 of the tibia 30 and on the lateral malleolus 41 of the fibula 40, with the leg 25 being bent at the knee. By having the leg bent at the knee, the tibia 30 stands on the posterior condyles 26 of the femur 20. Therefore, an assumption is made wherein an aligned midpoint of the medial and lateral malleoli points is said to define a plane (i.e., 30 sagittal plane) with the anatomical axis, with an axis of the knee being normal to the sagittal plane. The frontal plane is perpendicular to the sagittal plane, with the anatomical axis lying therein. The transverse plane is perpendicular to the sagittal and frontal

planes, and can be positioned at any height. With the anatomical axis and the midpoint of the malleolus region digitized, the femoral coordinate system, i.e., the femoral frame of reference, is complete. It is noted 5 that it is not required to measure two points to obtain a midpoint of the malleolus region. As this latter point will be in the sagittal plane, the only requirement is that a point is taken at a midpoint of the malleolus region, and may thus be placed 10 approximately by the operator.

It is pointed out that the projection values described herein (e.g., inclination, anteversion, etc.) are based on the acetabular and the femoral coordinate systems. As it is contemplated to use alternative 15 methods of digitizing the acetabular and the femoral coordinate systems, in addition to the preferred methods of Step 116, the projection values would be related to the alternative acetabular and femoral coordinate system. For instance, another contemplated method for 20 creating coordinate systems is described in U.S. Patent Application No. 60/691,164, to Hodgson et al.

Other methods to gather information pertaining to surgical parameters are as follows. (1) The user 25 digitizes a point on the greater trochanter before dislocation and retakes the same point, with the leg aligned in the same orientation, after reduction. (2) The user digitizes a point on the greater trochanter before dislocation and the system helps the user to replace the leg in the same orientation after reduction. 30 The leg length and the offset are automatically computed when the leg is positioned in range of the initial position before dislocation. (3) The user digitizes many points near the greater trochanter before dislocation, the center of rotation of the acetabulum as

described in Step 112 and the same points after reduction. The system aligns these points and computes the leg length and the offset. Also, in each case, the CAS system may help the operator in placing the leg in a 5 required initial position.

In optional Step 108, a relative position between the pelvis and the femur is registered with respect to the trackable references. The leg is simply left in a straight position, to align with a 10 longitudinal axis of the body, and a relative position is acquired between tracking references secured to their respective bones.

In Step 110, the femur is dislocated from the pelvis, so as to expose the acetabulum 11 and the 15 femoral head 21 and neck 22.

In Step 112, a center of rotation is digitized for the acetabulum, by taking reference points on the surface of the acetabulum 11. Referring to Fig. 3, a surface digitizing tool used to digitize the reference 20 points on the surface of the acetabulum is generally shown at 150.

The surface digitizing tool 150 has a flexible film 152. The flexible film 152 is made of a grid forming a network of micro-sensor nodes 154. More 25 specifically, the micro-sensor nodes are nodes changing characteristics as a function of the shape of the flexible film 152. Accordingly, the overall shape of the flexible film 152 is calculable by determining the interrelations between adjacent nodes 154.

30 Various configurations are considered for the flexible film 152. According to one embodiment, the flexible film 152 is formed of a series of micro-pipes aligned to form a grid support by a substrate such as a textile or plastic film. Each micro-pipe contains an

electrolyte (e.g., NaCl, or like biocompatible electrolytes), varying in electrical characteristics (e.g., resistivity, capacity) as a function of pressure sustained by the micro-pipe (e.g., torsion resulting 5 from the deformation of the grid to match a surface). Each micro-pipe is divided in a plurality of micro-pipe sections wired to allow the detection of any variation in the electrical characteristics of the micro-pipe sections as a result of shape variations. As the 10 position of each micro-pipe section is known, it is then possible to generate a 3D model from the calculated shape variations.

In the micro-pipe embodiment, the size and spacing between micro-pipes are selected as a function 15 of the resolution required for the 3D model of the object. As an example, spacing ranging between 0.5 to 1.0 mm between adjacent micro-pipes is sufficient to obtain a suitable resolution for a femoral head of a diameter of 60 mm, in the event that the flexible film 20 152 is used in hip replacement or resurfacing surgery.

In another embodiment, the film is formed fs strands made of a substrate having variable characteristics when curved or bent. As an example, quartz crystal is a suitable substrate as its electrical 25 characteristics vary when subjected to pressure. Accordingly, it is considered to provide the flexible film 152 made of quartz crystal substrate with a mesh of electrical wires capturing the electrical characteristics, and variations thereof, for different 30 sections along the strand.

In another embodiment, the flexible film 152 is a metallic film associated with a mesh of electrical wires capturing the variations in electrical

characteristics at predetermined locations on the metallic film.

In another embodiment, the flexible film 152 has a mosaic of micro-elements arranged in a 5 predetermined pattern, an example of which is generally shown in Fig. 6, with micro-elements being illustrated by 152' having rectangular shapes (amongst other considered shapes), with the micro-elements aligned in a quasi-uniform pattern (single or multiple layers), and 10 sandwiched between charged plates. Each micro-element 152' has a positive end and a negative end, with the polarity being proportional to the pressure sustained by the flexible film as a function of its deformation. Scans are performed in both directions of alignment, 15 whereby a 3D model can be digitized from the result of both scans.

In another embodiment, the flexible film 152 is a mesh of optical fibers, with Braggs gratings distributed along each optical fiber. The light 20 captured at the exit of the optical fibers provides information on the deformation of the flexible film 152. A 3D model can be created by associating the positions of the Braggs gratings in the optical fibers to the deformation information obtained from the captured 25 light.

In order to determine the position of each node, the flexible film 152 is connected to a model generator, as will be described in further detail hereinafter, which will calculate the 3-dimension shape 30 of the flexible film 152 by determining the position of each node 154, to form a mesh of points.

In order to calibrate and relate the 3-dimensional model obtained from the flexible film 152 to a coordinate system, a trackable reference 156 is

secured to the flexible film 152 in a known relation. In the example of Fig. 3, the trackable reference 156, a passive trackable reference, is a known optical pattern, so as to be tracked for position and orientation by a 5 CAS system. Therefore, a resurfacing processing unit calculates the position and orientation of the 3-dimensional model with respect to the frames of reference by relating the points of the nodes 154 to the trackable reference 156.

10 As an alternative to the trackable reference 156, it is contemplated to provide an active tracker connected to the flexible film 152. For example, magnetic (e.g., electro-magnetic), infrared and RF emitters are considered for use as reference 156, 15 provided the use of such technologies is acceptable in emergency-room environments.

20 In order to have the flexible film 152 take the shape of the acetabulum, it is contemplated to cover a generally spherical resilient member with the flexible film 152. The combination of the flexible film 152 and resilient member is then fitted into the acetabulum, at which point the resilient member exerts an outward pressure forcing the flexible film 152 to take the shape 25 of the acetabulum.

25 The use of the surface digitizing tool 150 is advantageous in that the positions of points are gathered in one step, and therefore represent an economy of time. Moreover, as points are currently digitized one by one using a pointer, the risk of handling error 30 is increased. The resolution of the flexible film 152 is typically controlled and tested during its manufacturing. The flexible film 152 is either disposable or sterilizable for further uses. The surface digitizing tool 150 is not limited to being used

in resurfacing surgery, but may be used in a plurality of surgical procedures in which it is desired to digitize bone models. Moreover, it is also considered to use the surface digitizing tool 150 along with a 5 processing unit to generate digital models of objects other than anatomical parts. In many cases, the digital model does not need to be related to a position and orientation, whereby the surface digitizing tool 150 is not necessarily provided with the trackable 10 reference 156.

A center calculator (e.g., sphere fitter algorithm) is used to find the acetabular center of rotation from the 3-dimension shape obtained, and will be described hereinafter with the description of a hip 15 resurfacing CAS system. The acetabular center of rotation is therefore known as a function of the tracking reference on the pelvis 10. In order to ensure precise results, it may be required that a predefined number of points be taken until validation criteria are 20 met. Visual validation of the sphere found by the algorithm can also be performed. The center of rotation and the diameter found may be displayed. Points are digitized in the fossa (depth of the acetabulum). If the center of rotation of the acetabulum is known, it is 25 not necessary to digitize the center of rotation of the femoral head. However, it can be done without departing from the spirit of the present embodiment.

In Step 114, the acetabulum is altered in view of accommodating the acetabular cup implant. In order 30 to guide the operator in altering the acetabulum, reamer position and orientation information is preferably provided, such that an axis of actuation of the reamer is for instance visually displayed. The previous acetabular center of rotation is known as a function of

the tracking reference secured to the pelvis 10, as it was acquired in previous Step 112. Preferably, the reamer is tracked for position and orientation.

Examples of information that can be provided 5 to the operator are as follows: generic 2D images, mosaic or mesh in 3D viewers along with drive shaft/reamer assembly in real time and/or display targeting views to help the user to align with target values, frontal and lateral views, inclination, 10 inclination adjusted with the pelvic tilt, anteversion, anteversion adjusted with the pelvic tilt angles in real time, 3D position of the reamer center of rotation relatively to the acetabulum center of rotation, the distance between the reamer pole and acetabular wall.

15 The diameter of the pelvic implant chosen by the surgeon can be used to display a position of the new acetabular center of rotation in comparison to the digitized acetabular center of rotation (Step 112). For instance, the distance between the centers of rotation 20 can be displayed numerically (e.g., in mm) as a function of the acetabular coordinate system digitized in previous Step 106. Also, the anteversion and inclination of the actuation axis of the reamer, both as a function of the acetabular coordinate system, can be 25 given numerically (e.g., in degrees) to guide the surgeon in the reaming. More precisely, the anteversion is calculated as the angle between the axis of the reamer and the pelvic frontal plane, and the inclination is the angle between the reamer axis projected onto the 30 acetabular frontal plane and a cranial-caudal axis (Step 106).

Step 116 consists in the insertion of the pelvic implant in the acetabulum 11, but it is pointed out that this step can also be performed once the

femoral head implant has been secured to the femur, according to the preference of the operator. A tracked impactor is preferably used. As the pelvic implant size is known, the diameter thereof and the known relation 5 between the impactor and the pelvic implant is used with the tracking of the impactor to give the anteversion and the inclination of the pelvic implant. Also, the distances between the current and the digitized centers of rotation can be displayed. Therefore, the surgeon is 10 guided during the use of the impactor so as to position the pelvic implant to a given position of the center of rotation thereof, and to a given orientation [with respect to anteversion and inclination] to provide a maximal range of motion and stability of the leg.

15           Although the pelvic implant is secured at this point to the pelvis 10, it is possible to adjust the position and orientation of the pelvic implant. Firstly, the tracked impactor, handle or like tool may be reconnected to the pelvic implant to serve as a lever 20 in manipulating the pelvic implant with the tracked impactor, allowing position and orientation information (e.g., anteversion and inclination) to be calculated from the tracking of the impactor. Alternatively, points on the circular edge of the pelvic implant may be 25 digitized to define a plane, with the normal to this plane being used to calculate the anteversion and the inclination, as suggested previously to obtain this information for the acetabulum.

30           Information typically provided with the use of the impactor includes: Display of generic 2D images, mosaic or mesh in 3D viewers along with impactor/cup assembly in real time and/or display targeting views to help the user to align with target values, frontal and lateral views, navigation of the impactor and cup,

display of inclination, inclination adjusted with the pelvic tilt, anteversion, anteversion adjusted with the pelvic tilt angles in real time, display of the 3D position of the cup center of rotation relatively to the 5 acetabulum center of rotation.

In Step 118, a bone model is digitized for the femoral head 21 and neck 22. The surface digitizing tool 150 is preferably used to create a 3-dimensional model of the femoral head 21 and neck 22. In this 10 embodiment, it is preferred to simply cover the femoral head 21 and neck 22 with the flexible film 152.

As tracking references have been secured to the femur 20 and the pelvis 10 in Step 104, the points on the surface of the femoral head 21 are known as a 15 function of the tracking of the respective tracking reference of the femur 20. As will be described hereinafter, a digital model of the femoral head and neck is produced, and may be displayed visually by the hip resurfacing CAS system.

20 It is pointed out that the neck/head connection is preferably identified in the digital model of the femoral head and neck. Information preferably obtained includes the lateral aspect of femur at the greater trochanter and the following 10 cm distally (as 25 far as possible), internal aspect of femur at the lesser trochanter and the following distal region, and femoral neck itself (varus/valgus, anteversion). The head-neck junction is digitized or computed based on the points taken. If points are acquired automatically, collection 30 of points can be taken by painting the femur. If points are acquired to build a mesh, points are taken on all the surface of the femur and not only on the frontal and transverse plane. The mesh can be constructed while

points are acquired so users may take more points to have a more precise reconstruction.

The center of rotation of the femoral head may also be calculated from the digital model, for instance 5 using a sphere fitter algorithm. If the center of rotation of the acetabulum is known, it may not be necessary to digitize the center of rotation of the femoral head.

In Step 120, the desired guide orientation is 10 determined. More specifically, the resurfacing of the femoral head will be dependent on the orientation of a guide wire. Therefore, computer assistance is provided to the operator so as to orient the guide wire in view of the subsequent resurfacing of the femoral head.

15 Referring to Fig. 5, a drill guide positioning frame is generally illustrated at 170. The drill guide positioning frame 170 is provided to facilitate the planning of the desired guide orientation, and to guide the drilling operation.

20 The drill guide positioning frame 170 has legs 172 supporting an annular support 174. The three legs 172 illustrated in Fig. 5 are displaceable and securable to the annular support 174, so as to hold the support 174 fixed about the femoral head 21 in the manner 25 illustrated in Fig. 5.

In the illustrated embodiment, the legs 172 each have an abutment end 176 that will contour a part 30 of the femoral neck 22. The abutment ends 176 may be brought toward a common center by actuation of the lockable degrees-of-freedom (DOF) between the legs 172 and the annular support 174 so as to clamp onto the femoral neck 22. In a preferred embodiment, two translational DOFs are provided between the combination of the legs 172 and the support 174, such that the

support 174 is displaceable in its plane. For instance, an actuator 177 is provided to actuate both translations DOFs.

In another embodiment, flexible film such as 5 described in the surface digitizing tool 150 is provided on the abutments ends 176. In such a case, the flexible film is used to obtain the surface model of the femoral neck 22, at the surfaces of contact between the positioning frame 170 and the femoral neck 22. In such 10 an embodiment, the position and orientation of the positioning frame 170 is tracked so as to relate the 3-dimensional surface data calculated from the flexible film to the frame of reference of the femur.

An alignment tube 178 is generally centrally 15 positioned in the annular support 174. The alignment tube 178 is supported to the support 174 by a spherical joint 180, so as to be displaceable in two rotational DOFs. The two rotational DOFs are lockable, so as to set a desired orientation for the alignment tube 178. 20 The alignment tube 178 is sized so as to accommodate a drill and like tools having an elongated stem. Therefore, the drill received in the alignment tube 178 is displaceable axially along the tube 178 so as to perform a drilling action.

In an embodiment, the support 174 is displaced 25 in its plane by displacement with respect to the legs 172 so as to have the alignment tube 178 in a suitable approximate position with respect to where a guide hole must be drilled into the femoral head 21. The 30 translational DOFs are then locked, in such a way that the only actuatable DOFs are the rotational DOFs of the spherical joint 180.

The drill or like registration tool is received in the alignment tube 178, and its longitudinal

axis is tracked. Accordingly, the orientation of the drill is adjustable by the movement of the drill in the two rotational DOFs of the spherical joint 180. The support 174 may also be released from its locking 5 relation with the legs 172 to adjust the position of the alignment tube 178 in the plane of the support 174.

Once a desired orientation of the alignment tube 178 is reached as obtained from the racking of the drill or like tool inserted in the alignment tube 178, 10 the DOFs are locked whereby the drilling step may be performed.

It is pointed out that it is contemplated to motorize all or some of the DOFs of the drill guide positioning frame 170 to enable precise positioning of 15 the alignment tube 178 with respect to the femoral head 21.

In order to plan the orientation of the guide wire, various views are provided such as the frontal and top views of the reconstructed femur. A template of the 20 femoral implant over the femur model is also provided, as well as the following information: the initial CCD and anteversion angles, an initial template position, orientation and size with respect to the femoral center of rotation. The CCD is calculated as the angle between 25 the projection of the guide wire on the femoral frontal plane and the longitudinal axis of the femur. Widgets are provided on screen to translate and rotate the template in each view. Selectors are provided to set the size of the implant and the neck diameter. If no 30 flexible film is used in the positioning frame 170, the neck diameter is found by two moving lines parallel to the template axis on the digitized bone model. When the lines are on the contour of the neck, the diameter is determined. The CCD and anteversion angles are computed

and displayed while the user is positioning the template. It is also contemplated to provide means to rotate the model so it can be viewed in 360 degrees. Implant position, orientation and size are computed and 5 suggested to the operator as information to consider. Information that is preferably computed and displayed includes: the estimated range of motion, the estimated final leg length and offset, a graphical representation of the femoral preparation (final result). Potential 10 dislocation and/or impingement is identified based on the cup position and orientation and the planned position and orientation of the femoral implant. If the femur is reconstructed with a mesh, the percentage of coverage may be provided. Indications of where notching 15 may happen should also be provided.

In Step 122, the femur is altered for the insertion of the guide wire, using the positioning frame 170 as described previously (Fig. 3). In order to guide the operator in positioning and orienting the guide wire 20 as planned, various information is provided, such as: generic 2D images, mosaic or mesh in 3D viewers along with guide wire/drill guide in real time and/or display targeting views to help the user to align with planned values, frontal and top views of the reconstructed 25 femur, navigation of the guide wire with a drill guide, the CCD and anteversion angles, alignment views of the guide wire tracked with the drill guide on the CCD and anteversion axis found during the planning phase (aligning "bull's-eyes" or axes), the CCD and 30 anteversion angles of the guide wire, audio and/or visual cues to let the operator know he/she is "in range" near the targeted angles by the means, the depth of the guide wire so the operator will be able to determine when the tip of the guide wire is near the

lateral cortex of the proximal femur, potential notching with audio and/or visual feedback, and where this notching could potentially occur.

The same information can be provided for the 5 insertion of a cannulated drill guide, with a display of the depth of drilling so the user will be able to determine when to stop drilling according to the chosen implant size.

Haptic devices can be used to ensure that the 10 drilling only occurs when the orientation of the guide wire is as planned.

In Step 124, the femoral head 21 is resurfaced, by way of a reamer. It is contemplated to provide visual information to the operator at this step. 15 However, the guides inserted in the femur ensure that the reaming follows planning. It is preferred that the operator keeps inspecting the actual femur especially during the cylindrical reaming, so as to avoid notching of the femoral neck 22. Information that can be 20 provided is as follows: Tracking for position and orientation of the cylindrical reamer, generic 2D images, mosaic or mesh in 3D viewers along with cylindrical reamer in real time, frontal and top views of the reconstructed femur, navigation of the 25 cylindrical reamer to track the reamed depth, orientation and position, the CCD and anteversion angles, a graphical representation of the result of the reaming, a pre-notching warning system based on probability to notch the cortex when the instrument is 30 close to it.

For the planar reaming, information that can be provided is as follows: generic 2D images, mosaic or mesh in 3D viewers along with planar reamer in real time, frontal and top views of the reconstructed femur,

tracking of the planar reamer to track the reamed depth, orientation and position, the CCD and anteversion angles, the distance between the head-neck junction and the plane surface of the planar reamer, indications to 5 the operator to stop reaming based on the selected implant size, how much bone has been removed, the leg length and the offset based on the position of the planar reamer, a graphical representation of the result of the reaming, pre-notching warning system based on 10 probability to notch the cortex when the instrument is close to it.

In Step 126, the femoral implant is secured to the resurfaced femoral head. Information that can be provided is as follows: position and orientation of the 15 femoral component, generic 2D images, mosaic or mesh in 3D viewers, frontal and top views of the reconstructed femur, navigation of the cement mantel to track the position and the orientation of the implant, the distance between the implant and the plane surface of 20 the femur, the leg length and the offset. It is contemplated to provide the possibility to attach the femoral implant while in place.

Although not illustrated in the method, there is provided the possibility to ream again the acetabulum 25 after the placement of the femoral component if the initial reaming is not adequate, following the options provided in Step 114. Also, Step 116 could be performed at this point. Information that can be provided includes: the leg length and the offset based on the 30 position of the reamer relatively to the acetabulum center of rotation and the position and orientation of the femoral implant with respect to the femur.

In the event that the acetabular cup is implanted at this point, the information that can be

provided is as follows: tracking of the cup impactor, generic 2D images, mosaic or mesh in 3D viewers along with impactor/cup assembly in real time and/or display targeting views to help the user to align with target 5 values, frontal and lateral views, display inclination, inclination adjusted with the pelvic tilt, anteversion, anteversion adjusted with the pelvic tilt angles in real time, 3D position of the cup center of rotation relatively to the acetabulum center of rotation, the leg 10 length and the offset based on the position of the impactor relatively to the acetabulum center of rotation and location of the femoral component on the femur.

In Step 128, an analysis of range of motion is performed. Information is calculated, such as the range 15 of motion of the joint after reduction, inclination, rotation and flexion/extension, possible dislocation (i.e., detect if the center of rotation has moved) and/or impingement.

Referring to Fig. 4, a hip resurfacing CAS 20 system is generally shown at 200. The CAS system 200 has a resurfacing processing unit 201. The resurfacing processing unit 201 is typically a computer or like device having a processor.

Peripherals are provided in association with 25 the resurfacing processing unit 201. In view of the trackable references 202 that will be secured to the femur and pelvis to define frames of reference (Steps 104 and 106) and to the tracked tools 204 used throughout the method 100, tracking apparatus 206 is 30 connected to the processing unit 201. The tracking apparatus 206 is provided to track the trackable references 202 and the tools 204 in the selected surgical environment. The tracking apparatus 206 may be

any of optical sensors, RF sensors, magnetic sensors and the like used in CAS systems.

Interface 207 is connected to the processing unit 201. The interface 207 enables data entry and 5 communications from the operator/surgeon of the system 200 to the processing unit 201. For instance, the interface 207 may be a keyboard, mouse and/or touch screen or the like.

A display unit 208 is connected to the 10 processing unit 201. The display unit 208 provides information to the operator/surgeon throughout the steps of the method 100. The data may be in the form of numerical values, as well as virtual representations of bone models along with simulations of tools. Further 15 detail about the data displayed by the display unit 208 will be given hereinafter.

The resurfacing processing unit 201 has a CAS controller 210. The CAS controller 210 is connected to the tracking apparatus 206 and to the interface 207, so 20 as to receive information therefrom. More specifically, the CAS controller 210 receives tracking data from the tracking apparatus 206, which tracking data will be interpreted by the processing unit 201. The CAS controller 210 receives user commands given by the 25 operator of the system 200 using the interface 207, and essentially controls the flow of information between the peripherals 206 to 208, and between the other components 212, 214, 216, and 218 of the resurfacing processing unit 201. The CAS controller 210 performs certain tasks 30 as well, such as calibration of tools.

The CAS controller 210 is also connected to the display unit 208. The CAS controller 210 provides display data, in the form of numerical values and visual

representations, to the display unit 208. The display unit 208 displays this information.

A position/orientation calculator 212 is connected to the CAS controller 210. The 5 position/orientation calculator 212 receives the tracking data of the tracking apparatus 206 from the CAS controller 210. The information provided to the CAS controller 210 by the position/orientation calculator 212 is in the form of the position/orientation of a 10 selected item of the trackable references 202 or tools 204. For instance, following the method 100, the data provided by the calculator 212 may be the pelvic and femoral coordinate systems from the trackable references 202. As another example, the data takes the form of a 15 real-time orientation of the operating axis of one of the tools 204, such as the axis of a reamer, or a real-time position of a tip of one of the tools 204, such as a registration pointer.

A center calculator 214 (i.e., a surgical 20 parameter calculator 214) is associated with the CAS controller 210. The center calculator 214 is provided to digitize the center of rotation of the pelvis (as described for Step 112) and the center of rotation of the femoral head (optionally in Step 118). The center 25 calculation is performed using the position/orientation data calculated by the position/orientation calculator 212, as well as commands from the CAS controller 210.

In the embodiment of Fig. 3, the center calculation is performed using the surface digitizing 30 tool 150 and/or the positioning frame 170 which provide meshes of points representing the surface of the acetabulum (Step 112), of the femoral head and neck (Step 118), and of the femoral neck (Step 122). An indication that the center calculation is to be

performed by the center calculator 214 is commanded by the CAS controller 210, for instance as a response to a command from the operator using the interface 207. The position of the centers is therefore calculated with 5 respect to the coordinate systems (Step 106), and the information is updated in real-time by the CAS controller 210.

A model generator 216 is associated with the CAS controller 210 and with the position and orientation 10 calculator 212 in a model generator system. The model generator 216 receives the signals representing the meshes of points from the flexible film (of the tool 150 or the frame 170) in combination with commands from the CAS controller 210, following Steps 112, 118 and 122. 15 The model generator creates 3-dimensional models from these signals, and combines the model to the position and orientation of the trackable member 156 to relate the bone model to the frames or reference. For instance, in Step 118, a surface model of the femoral 20 head and neck is obtained. The surface model is associated with the coordinate systems obtained from the tracking of the trackable references 202.

More specifically, the model generator 216 obtains a signal from each of the micro-sensor elements 25 when the film is shaped to model the femoral head and neck and/or the acetabulum. The signals are used, along with the individual position of each of the micro-sensor element, to determine a shape variation of the film at each of the micro-sensor element. Subsequently, the 3D 30 model of the bone element(i.e., femoral head/neck, acetabulum) is generated from the shape variation and the individual position of each of the micro-sensor elements.

A resurfacing evaluator 218 is provided in association with the CAS controller 210. The resurfacing evaluator 218 is provided to determine the evaluated bone resurfacing alteration, which is the 5 effect of a resurfacing tool (from the tools 204) on the bone model. Accordingly, bone model data is provided by the model generator 216, along with the position and orientation of a reaming tool as determined by the CAS controller 210 from tool geometry data and an 10 orientation of a bone-altering tool (such as a drill) from the tools 204.

In the case of femoral head resurfacing, as the precision of the reaming must be respected, it has been described previously that a guide wire is provided, 15 in order to drill a guiding bore in the femoral head prior to reaming. Therefore, the evaluated bone resurfacing alteration is indicated as a function of the orientation of the axis of the drill guide. Therefore, information associated with a potential wrongful reaming 20 is provided to the operator, such that the operator is guided into drilling the drill guide in a suitable orientation in view of the effects on resurfacing. The resurfacing evaluator 218 may also be used to calculate the effect of acetabulum reaming on associated data 25 (pelvic center of rotation, anteversion, etc.)

Throughout surgery, the display unit 208 provides the data discussed above. For instance, the output of the model generator 210 is converted by the CAS controller 210 to a virtual model of the bone 30 surface to be altered, for instance with virtual real-time representations of the tools with respect to the bone models. Accordingly, warning can be signaled to the operator/surgeon if the effects of resurfacing are outside acceptable standards. Again, in femoral head

resurfacing, the femoral neck must not be nicked, whereby drill guide axis data can be associated with a warning signal to guide the operator/surgeon in adjusting the orientation of the drill.

5 Moreover, numerical information is also provided to the operator, which numerical information is described previously for the steps of the method 100.

10 Various instruments can be used, such as blunt tracked pointers (straight or curved), adapted to fit on a rotational tracker or a universal handle to paint bones (acetabulum, femur, etc.). The drill guide or guides can be designed to fit on a universal handle or a rotational tracker. A mechanism may be used to block/hold the position and the orientation of the drill 15 guide. Planar reamer is modified to be used in conjunction with the rotational tracker. Technology to have appropriate drilling instrument if the user wants to navigate the drill bit only.

20 In other contemplated options there are the possibility to navigate the guide wire, the guide wire and the cannulated drill bit or only the drill bit, the possibility to rotate, translate and zoom the viewers, the animation or illustration to describe to the operator the upcoming tasks, the possibility to take 25 snapshots, menus allowing selection of options and parameters during the procedure, allowing navigating through the surgical steps in the application, step-driven (wizardlike sequence of pages), status icons to display tracking state of an instrument, volume view/aim 30 camera to display in space the location of the trackers seen by the camera, give information on the tracked state of a tracker (out of volume, missing sphere, IR interference, etc).

## CLAIMS:

1. A model generator system for generating models of objects, comprising:

5 a surface digitizing tool having a film of micro-sensor elements, with each micro-sensor element related in a network affected by a shape of the film, the film being flexible to conform to a shape of a selected surface of an object;

10 a processing unit for receiving signals from the micro-sensor elements of the network, the processing unit having a model generator producing a model of the selected surface of the object from the signals of the network of resistive elements.

15 2. The model generator system according to claim 1, further comprising a tracking apparatus, and wherein:

20 the surface digitizing tool has a trackable reference connected to the film in a known relation, the trackable reference being tracked by the tracking apparatus; and

25 the processing unit receives tracking data for the trackable reference and further comprises a position/orientation calculator to calculate from the tracking data a position and orientation of the trackable reference, with the model generator receiving said position and orientation data of the trackable reference to associate the position and orientation data to the known relation between the film and the trackable reference to provide a position and orientation of the selected surface of the object.

3. The model generator system according to claim 2, wherein the tracking apparatus is a passive optical tracking apparatus, and the trackable reference is a selected pattern of retro-reflective spheres.

5 4. The model generator system according to claim 1, wherein the object is a bone element and the model generator system is used in computer-assisted surgery.

10 5. The model generator system according to claim 4, wherein the surface digitizing tool has a resilient body, the film of micro-sensors being mounted on the surface of the resilient body, the surface digitizing tool being used to conform to the shape of a bone element cavity with the resilient body deforming to 15 enter the cavity and applying resilient forces against a surface of the cavity, whereby the film of micro-sensors conforms to the shape of the cavity.

15 6. The model generator system according to claim 5, wherein the bone element cavity is an acetabulum.

20 7. The model generator system according to claim 4, wherein the surface digitizing tool is used with a bone element having a generally semi-spherical shape, and the processing unit has a center calculator 25 for receiving the model of the selected surface of the bone element and determining a center of the bone element from said model.

25 8. The model generator system according to claim 7, wherein the bone element is any one of an acetabulum and a femoral head.

9. The model generator system according to claim 1, wherein the micro-sensors are resistive elements.

10. The model generator system according to 5 claim 1, wherein the micro-sensors are capacitive elements.

11. A positioning frame for aligning a position and orientation of a drilling tool with respect to a bone element, comprising:

10 a connector portion adapted to releasably grasp the bone element;

a support portion operatively connected to the connector portion and positioned with respect to a portion of the bone element to be drilled;

15 an alignment tube operatively connected to the support portion, the alignment tube being adapted to receive a working end of a drill to align the drill with the bone element; and

20 joints between the alignment tube and the connector portion to adjust a position and an orientation of the alignment tube with respect to the bone element.

12. The positioning frame according to claim 11, wherein the joints comprise at least one joint providing 25 at least two translational degrees of freedom between the connector portion and the alignment tube to adjust a position of the alignment tube, the two translational degrees-of-freedom being lockable.

13. The positioning frame according to claim 12, further comprising degrees of actuation to control and actuate the at least two translational degrees of freedom.

5 14. The positioning frame according to claim 11, wherein the joints comprise at least one joint providing at least two rotational degrees of freedom between the connector portion and the alignment tube to adjust an orientation of the alignment tube, the two rotational  
10 degrees-of-freedom being lockable.

15. The positioning frame according to claim 11, wherein ends of the connector portions grasping the bone element each have a film of micro-sensor elements, with each micro-sensor element related in a network affected by a shape of the film, the film being flexible to conform to a shape of the bone element so as to provide data pertaining to a geometry of the bone element.

16. The positioning frame according to claim 11, wherein the bone element is a femur, and the connector  
20 portion releasably grasp a femoral neck of the femur, and the alignment tube is aligned with a femoral head of the femur.

17. The positioning frame according to claim 11, wherein the joints provide four degrees of freedom  
25 between the alignment tube and the connector portion, with at least two degrees of actuation to actuate and control two selected ones of the degrees of freedom.

18. The positioning frame according to claim 11, wherein the support portion has annular body, with the  
30 alignment tube being held generally in a center of the

annular body, and wherein the connector portion has three legs projecting from the annular body.

19. A method for drilling a bone element in computer-assisted surgery, comprising:

5 providing a positioning frame having a drill guide with adjustable degrees of freedom for the drill guide in the positioning frame, and a computer-assisted surgery system providing orientation data associated with tracking of the drill guide and of a frame of  
10 reference of the bone element;

clamping the positioning frame to the bone element such that the drill guide is in the vicinity of a portion of the bone element to be drilled;

15 displacing the drill guide along the degrees of freedom as a function of the orientation data from the computer-assisted surgery, until a desired orientation is reached for the drill guide; and

drilling the bone element by passing a drill bit through the drill guide in the desired orientation.

20 20. The method according to claim 19, wherein displacing the drill guide comprises inserting a drill bit of a drill in the drill guide and moving the drill and the drill guide concurrently.

21. The method according to claim 20. wherein  
25 providing orientation data comprises calculating the orientation data as a function of a tracking of the drill.

22. The method according to claim 19, wherein  
displacing the drill guide comprises locking the degrees  
30 of freedom at the selected orientation.

23. The method according to claim 19, wherein displacing the drill guide comprises actuating degrees of actuation to actuate the degrees of freedom.

24. The method according to claim 19, wherein 5 clamping the positioning frame comprises clamping the positioning frame to a femoral neck, such that the drill guide is in the vicinity of a femoral head as the femoral head is drilled.

25. A method for generating a model of an object 10 comprising:

providing a film of micro-sensor elements, with an individual position in the film of each said micro-sensor element known;

15 obtaining a signal from each said micro-sensor element when the film is shaped to model an object;

determining a shape variation of the film at each said micro-sensor element from the signal; and

20 generating a model of the object from the shape variation and the individual position of each said micro-sensor element.

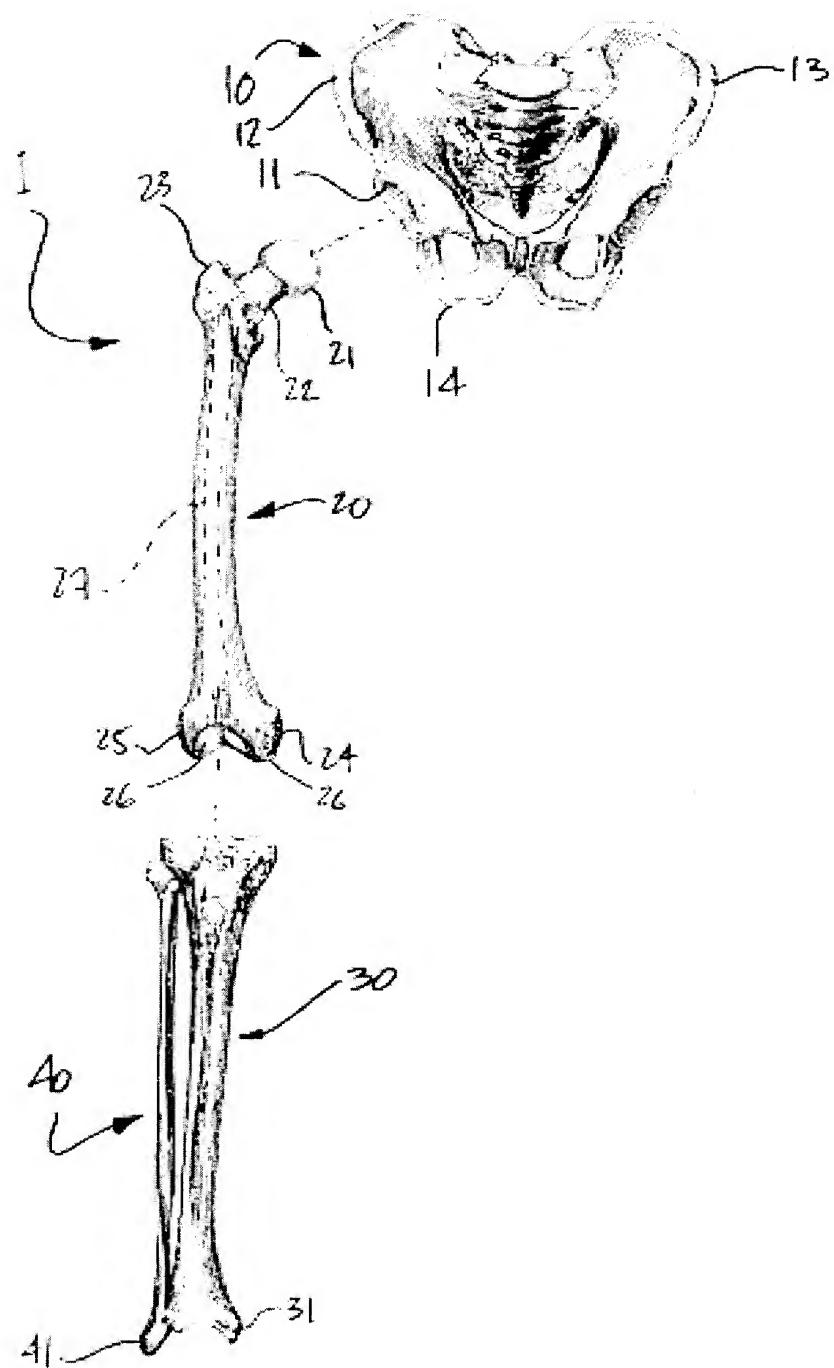
26. The method according to claim 25, wherein providing comprises providing a trackable reference connected to the film of micro-sensor elements, with a relation between the film and the trackable reference 25 known, and further comprising tracking the trackable reference, and calculating a position and orientation of the object from the model of the object and the tracking of the trackable reference.

27. The method according to claim 25, wherein 30 obtaining comprises obtaining a signal from each said

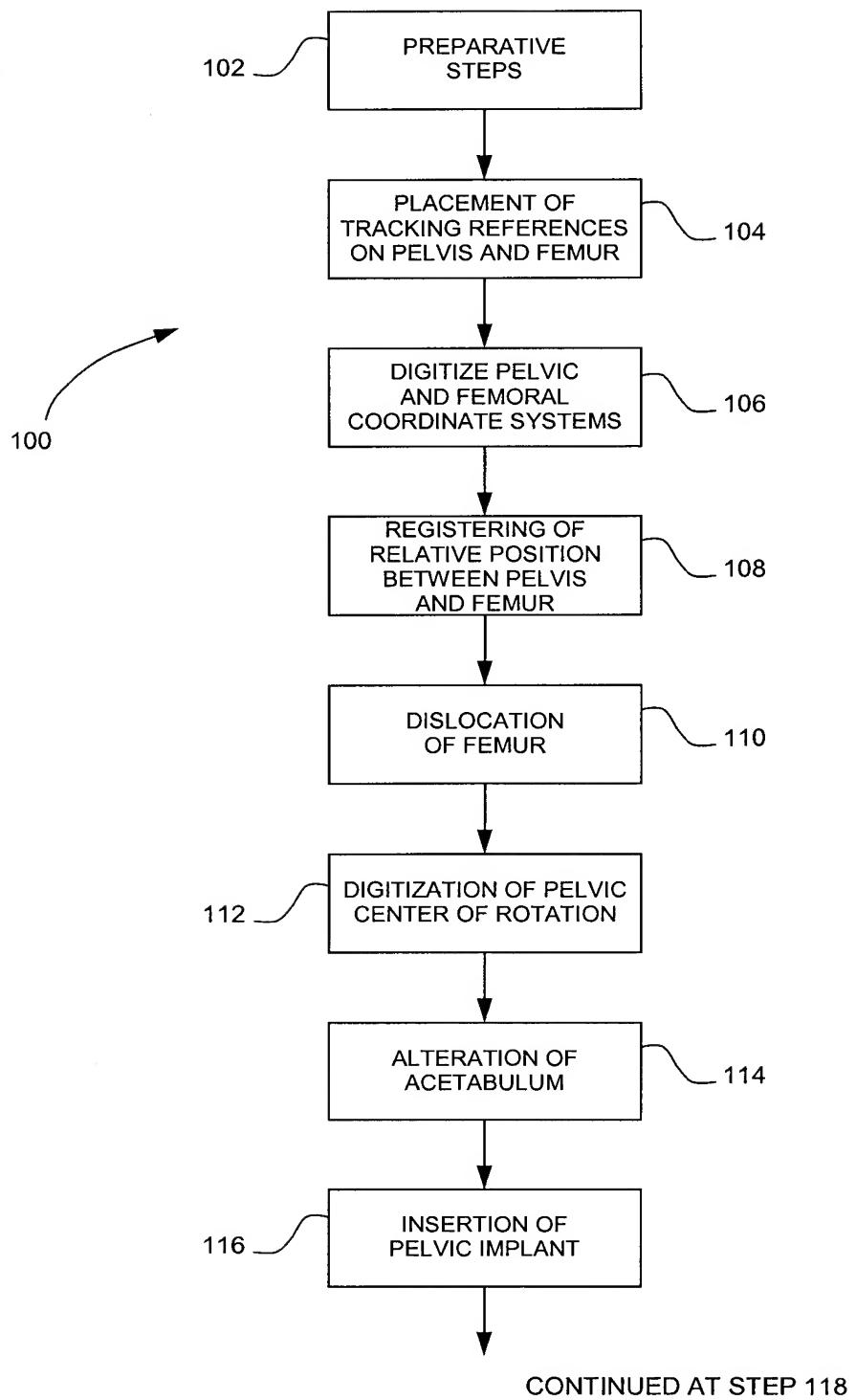
micro-sensor element when the film is shaped to model a bone element in computer-assisted surgery.

28. The method according to claim 27, wherein obtaining comprises obtaining a signal from each said 5 micro-sensor element when the film is shaped to model at least one of a femoral head and an acetabulum in computer-assisted hip replacement surgery.

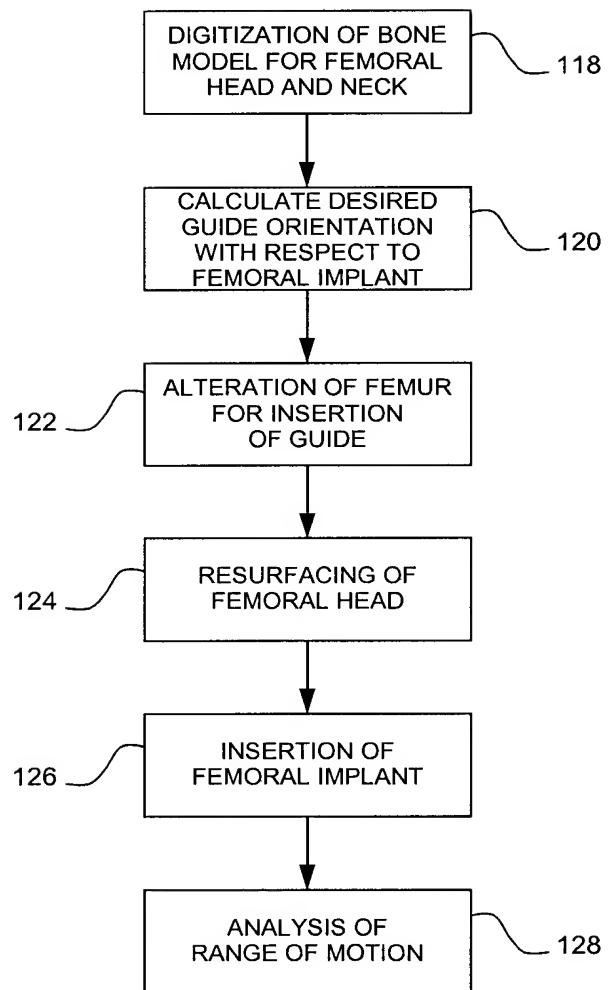
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**Fig. 1**

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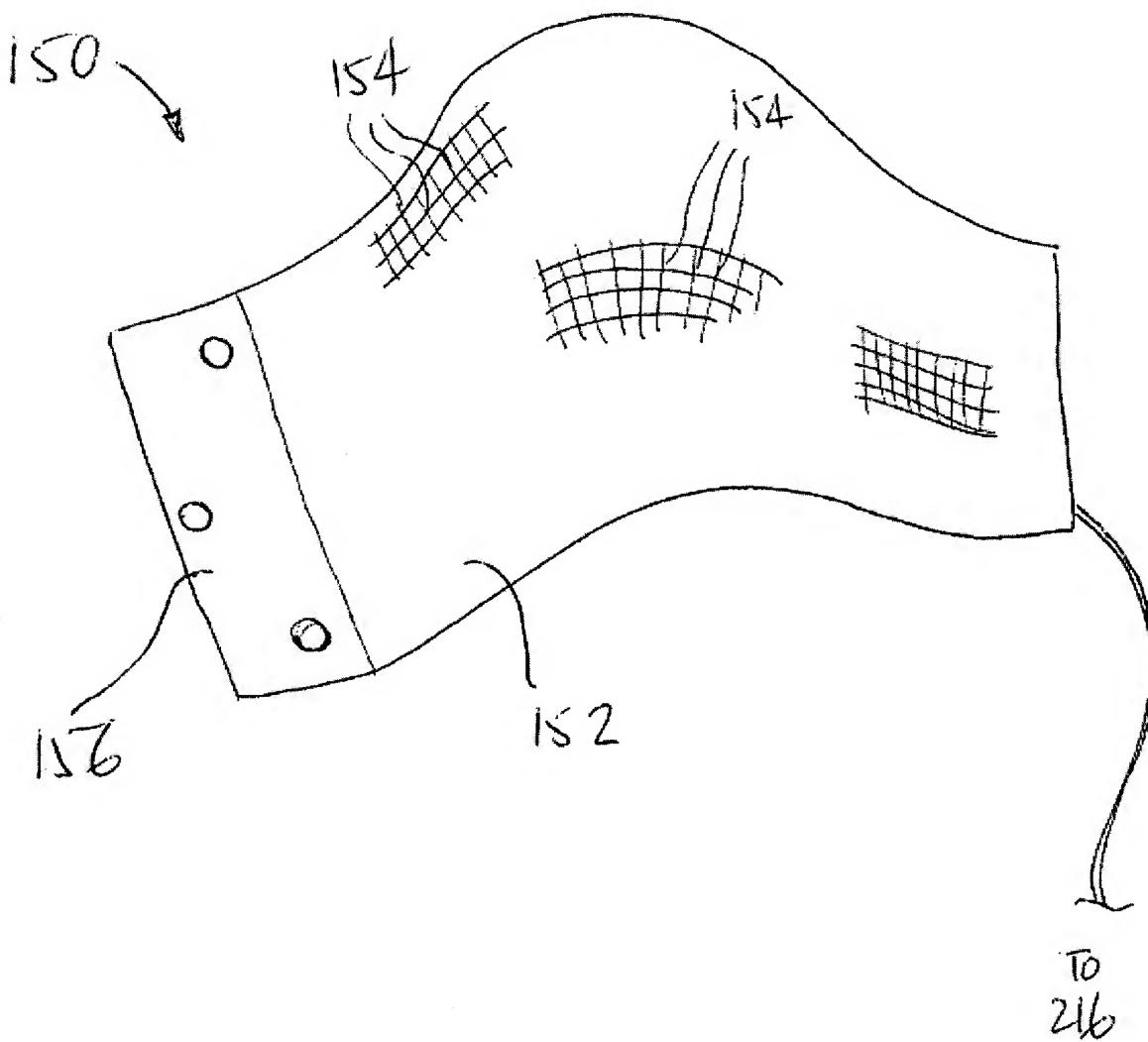
**Fig. 2**

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**Fig. 2 (cont'd)**

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**Fig. 3**

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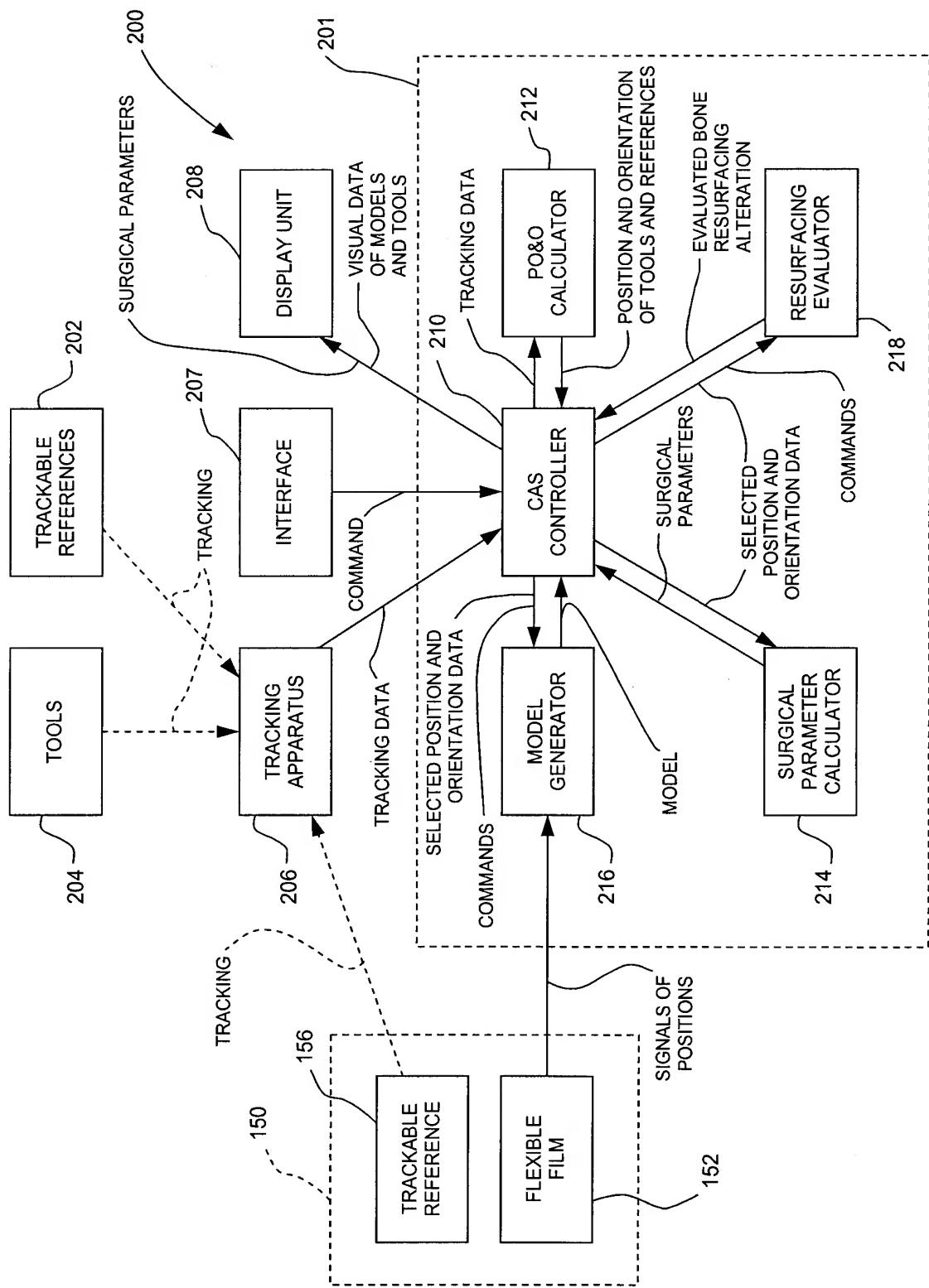


Fig. 4

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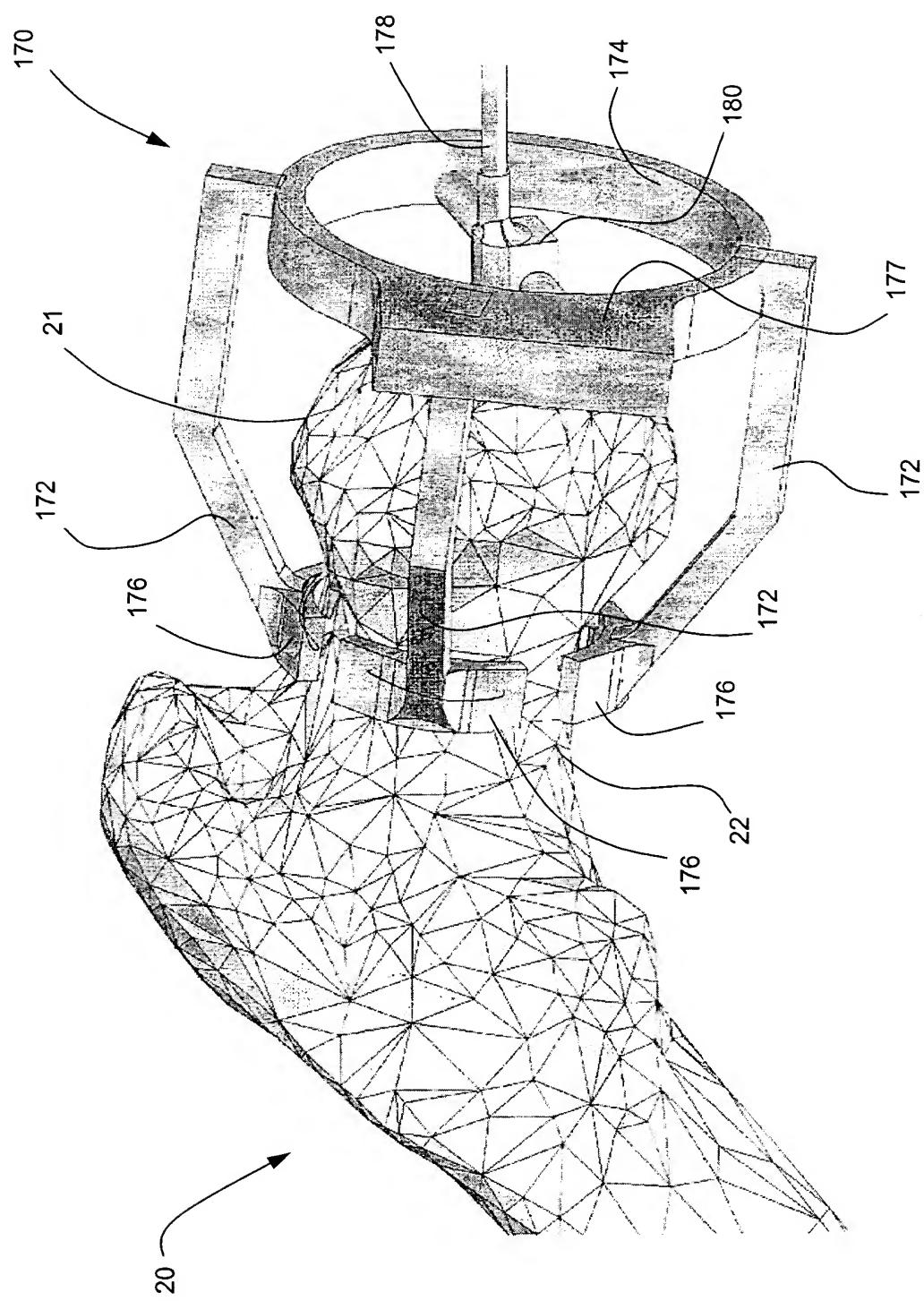
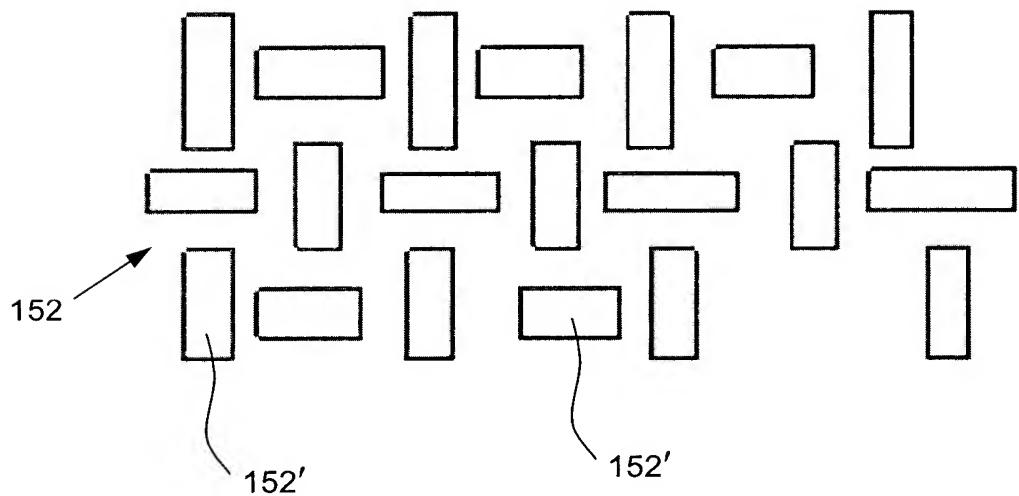


Fig. 5

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**Fig. 6**

**INTERNATIONAL SEARCH REPORT**

 International application No.  
 PCT/CA2007/001366

**A. CLASSIFICATION OF SUBJECT MATTER**

 IPC: **G01B 5/207** (2006.01), **A61B 17/17** (2006.01), **A61B 5/107** (2006.01), **G01B 7/287** (2006.01),  
**A61B 19/00** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

 IPC: G01B 5/207 (2006.01), G01B 7/287 (2006.01), G01B 5/20(2006.01), G01B 7/28(2006.01), A61B 17/17 (2006.01),  
 A61B 5/107 (2006.01), A61B 19/00 (2006.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

Questel-Orbit (FamPat), PAJ, Espacenet, WEST.

Keywords (bone, drill, surface)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	WO 2006095109 A1 (DAVID, D. et al) 14 September 2006 (14-09-2006) * Figure 1B, Pages 8-10 *	1, 4, 9-10 and 25-28
X	US 6127672 A (DANISCH, L.) 03 October 2000 (03-10-2000) * Figures 35-37, Column 2, lines 40-50 and Columns 5-6 *	1, 2, 4, 9-10 and 25-28
X	JP 2003279306 A (KATSUJI, K.) 02 October 2003 (02-10-2003) * English abstract, Figures *	1, 4, 9-10 and 25-28
A	US 4896663 A (VANDEWALLS, M.V.) 30 January 1990 (30-01-1990) * Entire Document *	11-18
A	US 5817098 A (ALBREKTSSON, B. et al) 06 October 1998 (06-10-1998) * Entire Document *	11-18
A	WO 2005027755 A1 (MOORE, G. et al) 31 March 2005 (31-03-2005) * Entire Document *	11-18

[ ] Further documents are listed in the continuation of Box C.

[ X ] See patent family annex.

* Special categories of cited documents :		
"A" document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

19 October 2007 (19-10-2007)

Date of mailing of the international search report

13 November 2007 (13-11-2007)

 Name and mailing address of the ISA/CA  
 Canadian Intellectual Property Office  
 Place du Portage I, C114 - 1st Floor, Box PCT  
 50 Victoria Street  
 Gatineau, Quebec K1A 0C9  
 Facsimile No.: 001-819-953-2476

Authorized officer

Yasin Bismilla 819- 934-6240

**INTERNATIONAL SEARCH REPORT**International application No.  
PCT/CA2007/001366**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons :

1.  Claim Nos. : 19-24 and 27-28

because they relate to subject matter not required to be searched by this Authority, namely :

Claims 19-24 and 27-28 are directed to a method for treatment of the human body by surgery and are not required to be searched by this Authority.

2.  Claim Nos. :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically :

3.  Claim Nos. :

because they are dependant claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows :

The claims are directed to a plurality of inventive concepts as follows:

Group A - Claims 1-10 and 25-28 are directed to a model generator system.

Group B - Claims 11-18 are directed to a positioning frame for aligning and orienting a drilling tool with respect to a bone element.

The claims must be limited to one inventive concept as set out in Rule 13 of the PCT.

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2.  As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos. :

4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos. :

**Remark on Protest**  The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
PCT/CA2007/001366

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
WO 2006095109A1	14-09-2006	FR 2883073A1	15-09-2006
JP 2003279306A	02-10-2003	None	
US 6127672A	03-10-2000	AU 6389098A CA 2200117A1 CA 2284085A1 CA 2284085C CN 1153952C CN 1250516A DE 69837752D1 DE 69837752T2 EP 0968400A1 EP 0968400B1 JP 3949731B2 JP 2001518185T WO 9841815A1	12-10-1998 17-09-1998 24-09-1998 02-12-2003 16-06-2004 12-04-2000 21-06-2007 18-10-2007 05-01-2000 09-05-2007 25-07-2007 09-10-2001 24-09-1998
US 4896663A	30-01-1990	None	
US 5817098A	06-10-1998	AT 257672T AU 693697B2 AU 5783196A BR 9608821A CA 2219116A1 CA 2219116C CN 1119124C CN 1184410A CZ 288799B6 CZ 9703623A3 DE 69631344D1 DE 69631344T2 DK 957782T3 EP 0957782A1 EP 0957782B1 ES 2213773T3 HU 220351B HU 9900303A2 HU 9900303A3 IS 4613A JP 3307399B2 JP 11500045T KR 100267823B1 NO 975173A NO 975173D0 NZ 308248A PL 183613B1 PL 323351A1 PT 957782T RU 2157665C2 SE 9501829D0 TR 9701374T1 WO 9636285A1	15-01-2004 02-07-1998 29-11-1996 15-06-1999 21-11-1996 10-10-2000 27-08-2003 10-06-1998 12-09-2001 17-06-1998 19-02-2004 02-12-2004 17-05-2004 24-11-1999 14-01-2004 01-09-2004 28-12-2001 28-05-1999 28-02-2001 15-12-1997 24-07-2002 06-01-1999 01-11-2000 11-11-1997 11-11-1997 27-05-1998 28-06-2002 30-03-1998 31-05-2004 20-10-2000 17-05-1995 21-02-1998 21-11-1996
WO 2005027755A1	31-03-2005	EP 1663021A1 GB 0322084D0 JP 2007505718T	07-06-2006 22-10-2003 15-03-2007